510(k) Summary of Safety and Effectiveness K052245

LAR Manufacturing, LLC
Orthodontic Ceramic Brackets

SEP 23 2005

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submission Correspondant:	Emergo Group Inc. 2454 McMullen Booth Road, Suite 427 Clearwater, FL 33759 USA
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Contact:	Ian Gordon Senior Vice President
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Submission Sponsor:	LAR Manufacturing, LLC 6828 Commerce Ave. Port Ritchey, FL 34668

Date Prepared	August 5, 2005

Name of device	Orthodontic Ceramic Brackets – Accent Series and Exceed Series Ceramic Brackets

Classification Names	Bracket, Ceramic, Orthodontic

Device Classification	Regulatory Class: II Product Code: NJM Classification Panel: Dental Regulation Number: 21 C.F.R. 872.5470

510(k) Summary of Safety and Effectiveness

LAR Manufacturing, LLC
Orthodontic Ceramic Brackets

Predicate Device(s)

510(k)#	Device	Manufacturer
K042178	Mystic Orthodontic Ceramic Brackets	Dentsply International

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Device Description

LAR Manufacturing, LLC Ceramic Brackets are available if the following prescriptions:

- Exceed Series Brackets
  - Roth .018" & .022" Slot Sizes

- Accent Series
  - Roth .018" & .022" Slot Sizes;
  - Edgewise .018" &.022" Slot Sizes;
  - Ricketts .018" Slot Size;
  - Bio-Progressive/Hilgers .018" & .022" Slot Sizes

The Exceed Series and Accent Series Ceramic Brackets are produced using Al_2O_3, translucent polycrystalline aluminum oxide (99.9%). These Ceramic Brackets are bonded to the teeth with commercially available materials and linked together by "archwire" that applies steady, gentle pressure to produce desired tooth movement.

Indications

LAR Manufacturing, LLC Orthodontic Ceramic Brackets are indicated for orthodontic movement of teeth.

Technological Characteristics

The function and performance of the LAR Manufacturing, LLC Orthodontic Ceramic Brackets are identical to the predicate device listed above. There is no difference in fundamental scientific technology. The LAR Manufacturing, LLC Orthodontic Ceramic Brackets are made of the same material as the predicate device currently on the market and has the same overall intended use.

Conclusion

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device.

There are no major differences between the LAR Manufacturing, LLC and the predicate device cited, and therefore the LAR Manufacturing, LLC Orthodontic Ceramic Brackets do not raise any questions regarding safety and effectiveness.

The LAR Manufacturing, LLC Orthodontic Ceramic Brackets, as designed, are as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2005

LAR Manufacturing, LLC
C/O Mr. Ian P. Gordon
Senior Vice President
Emergo Group, Inc.
2454 McMullen Booth Road, Suite 427
Clearwater, Florida 33759

Re: K052245
Trade/Device Name: Accent Series™ Ceramic Brackets and
Exceed Series™ Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: August 12, 2005
Received: August 17, 2005

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052245

Device Name: **Orthodontic Ceramic Brackets**

Indications for Use:

The LAR Manufacturing, LLC Orthodontic Ceramic Brackets are indicated for orthodontic movement of teeth.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052245